Complete Summary

GUIDELINE TITLE

Nausea and vomiting of pregnancy.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Nausea and vomiting of pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Apr. 13 p. (ACOG practice bulletin; no. 52). [94 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Nausea and vomiting in pregnancy, including hyperemesis gravidarum

GUIDELINE CATEGORY

Management Prevention Treatment

CLINICAL SPECIALTY

Internal Medicine Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the best available evidence about the diagnosis and management of nausea and vomiting of pregnancy

TARGET POPULATION

Pregnant women

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Prevention/Treatment

- 1. Differential diagnosis
- 2. Assessment of risk factors
- 3. Laboratory tests (in severe cases)
- 4. Ultrasound
- 5. Nonpharmacologic therapies
 - Rest
 - Avoidance of provoking stimuli
 - Frequent and small meals, avoiding spicy or fatty foods
 - Multivitamins taken at time of conception (for prevention)
 - Powdered ginger capsules
- 6. Pharmacologic therapies
 - Vitamin B₆ alone or combined with doxylamine
 - Dextrose or vitamin supplementation (particularly thiamine)
 - Antihistamine H₁ receptor blockers
 - Phenothiazines
 - Benzamides
 - Corticosteroids (last resort therapy)
- 7. Hospitalization (in severe cases)
- 8. Enteral or parenteral nutrition
- 9. Intravenous hydration

MAJOR OUTCOMES CONSIDERED

- Maternal/fetal morbidity and mortality
- Hospitalization rate
- Pregnancy termination rate
- Response rate to treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and December 2003. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Taking a multivitamin at the time of conception may decrease the severity of nausea and vomiting of pregnancy.
- Treatment of nausea and vomiting of pregnancy with vitamin B₆ or vitamin B₆ plus doxylamine is safe and effective and should be considered first-line pharmacotherapy.
- In patients with hyperemesis gravidarum who also have suppressed thyroidstimulating hormone levels, treatment of hyperthyroidism should not be undertaken without evidence of intrinsic thyroid disease (including goiter and/or thyroid autoantibodies).

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Treatment of nausea and vomiting of pregnancy with ginger has shown beneficial effects and can be considered as a nonpharmacologic option.
- In refractory cases of nausea and vomiting of pregnancy, the following medications have been shown to be safe and efficacious in pregnancy: antihistamine H₁ receptor blockers, phenothiazines, and benzamides.
- Early treatment of nausea and vomiting of pregnancy is recommended to prevent progression to hyperemesis gravidarum.
- Treatment of severe nausea and vomiting of pregnancy or hyperemesis gravidarum with methylprednisolone may be efficacious in refractory cases; however, the risk profile of methylprednisolone suggests it should be a treatment of last resort.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Intravenous hydration should be used for the patient who cannot tolerate oral liquids for a prolonged period or if clinical signs of dehydration are present. Correction of ketosis and vitamin deficiency should be strongly considered. Dextrose and vitamins, especially thiamine, should be included in the therapy when prolonged vomiting is present.
- Enteral or parenteral nutrition should be initiated for any patient who cannot maintain her weight because of vomiting.

Definitions:

Grades of Evidence

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

The original guideline document contains a clinical algorithm titled, "Pharmacologic treatment of nausea and vomiting of pregnancy."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Reduction in nausea and vomiting

POTENTIAL HARMS

 Phenothiazines were identified as a possible cause of malformations in one study, but the aggregate of studies attest to their safety.

- Although the evidence is not strong, doses of droperidol greater than 25 mg were associated with a prolonged Q-T interval that in some cases has led to the potentially fatal arrhythmia torsades de pointes. This drug should be used with caution.
- Three recent studies have confirmed an association between oral clefts and methylprednisolone use in the first trimester. The teratogenic effect is weak, probably accounting for no more than 1 or 2 cases per 1,000 treated women. Nevertheless, in view of this probable association, corticosteroid use for hyperemesis gravidarum should be used with caution and avoided before 10 weeks of gestation.
- Because life-threatening complications of parenteral nutrition have been described, it is reasonable to attempt enteral tube feeding initially.
- For women who need longer-term support and who cannot tolerate enteral tube feedings, the use of total parenteral nutrition has been described for hyperemesis gravidarum in case reports and 2 small series. A peripherally inserted central catheter can be used to avoid some of the complications of central access, but it is still associated with significant morbidity.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Apr

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

 Morning sickness. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2005.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site.</u>

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

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Date Modified: 11/3/2008

